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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-----------------|----------------------|-------------------------|------------------|
| 09/577,468 | 05/24/2000 | Vivien W. Wong | REG 142-C | 5396 |
| 26693 | 7590 09/26/2003 | | | |
| REGENERON PHARMACEUTICALS, INC 777 OLD SAW MEL RIVER ROAD TARRYTOWN, NY 10591 | | | ÉXAMINER | |
| | | | HAYES, ROBERT CLINTON | |
| TARRITO | W14,,141 10321 | | ART UNIT | PAPER NUMBER |
| | ! | | 1647 | 71 |
| | | | DATE MAILED: 09/26/2003 | d (|

Please find below and/or attached an Office communication concerning this application or proceeding.



09/577,468

Applicant(s)

Wong et al

Office Action Summary

Examiner

Robert C. Hayes, Ph.D.

Art Unit 1647



| The MAILING DATE of this communication appears on the cover sheet with the correspondence address | | | | | |
|--|--|--|--|--|--|
| Period for Reply | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. | | | | | |
| - Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. | | | | | |
| If the period for really specified shows is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. | | | | | |
| If the period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). | | | | | |
| Any reply received by the Office later than three months after the mailing date of this communical earned patent term adjustment. See 37 CFR 1.704(b). | tion, even if timely filed, may reduce any | | | | |
| Status | | | | | |
| 1) X Responsive to communication(s) filed on Jul 10, 2003 | · | | | | |
| 2a) ☐ This action is FINAL . 2b) ☑ This action is non | | | | | |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11; 453 O.G. 213. | | | | | |
| Disposition of Claims | | | | | |
| 4) X Claim(s) <u>1-4 and 8-11</u> | is/are pending in the application. | | | | |
| 4a) Of the above, claim(s) | | | | | |
| 5) Claim(s) | is/are allowed. | | | | |
| 6) X Claim(s) 1-4 and 8-11 | | | | | |
| 7) | is/are objected to. | | | | |
| 8) | | | | | |
| Application Papers | | | | | |
| 9) The specification is objected to by the Examiner. | | | | | |
| 10) ☐ The drawing(s) filed on is/are a) ☐ accepted or b) ☐ objected to by the Examiner. | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | |
| 11) The proposed drawing correction filed on | $_$ is: a) \square approved b) \square disapproved by the Examiner. | | | | |
| If approved, corrected drawings are required in reply to this Office action. | | | | | |
| 12) The oath or declaration is objected to by the Examiner. | | | | | |
| Priority under 35 U.S.C. §§ 119 and 120 | | | | | |
| 13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). | | | | | |
| a) ☐ All b) ☐ Some* c) ☐ None of: | | | | | |
| 1. Certified copies of the priority documents have been received. | | | | | |
| 2. Certified copies of the priority documents have been received in Application No. | | | | | |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage | | | | | |
| application from the International Bureau (PCT Rule 17.2(a)). *See the attached detailed Office action for a list of the certified copies not received. | | | | | |
| 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e). | | | | | |
| a) The translation of the foreign language provisional application has been received. | | | | | |
| 15) 🗹 Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121. | | | | | |
| Attachment(s) . | | | | | |
| 1) Notice of References Cited (PTO-892) 4) Inter- | view Summary (PTO-413) Paper No(s) | | | | |
| 2, | 5) Notice of Informal Patent Application (PTO-152) | | | | |
| 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s). 15 6) Other: | | | | | |

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

- 1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/10/03 has been entered.
- 2. The amendment filed 7/10/03 has been entered.
- 3. The rejection of claims 3, 7-12 & 18 under 35 U.S.C. 112, first paragraph, for lack of enablement is withdrawn due to the cancellation or amendment of the claims.
- 4. The rejection of claims 8-11 & 13 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn due to the cancellation or amendment of the claims.
- 5. The rejection of claims 1-4, 6-12, 18 & 20-22 under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter, is withdrawn due to either the cancellation or amendment of the claims, and due to Applicants' arguments.

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- 6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
- 7. Applicants' arguments filed 7/10/03 have been considered but are not found persuasive.
- 8. Claim 10 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Note that "intrathecal" administration is a broader concept than "administration... via the nasal or the respitatory passages", as recited in base claim 1.

- 9. Claim 10 is objected to because of the following informalities: "intratracheally" is misspelled. Appropriate correction is required.
- 10. Claims 1-4 & 8-11 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3 & 8-9 of copending Application No. 09/454380, for the reasons made of record in Paper NO: 10 (mailed 7/30/02) & 12 (mailed 3/31/03).

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Although the conflicting claims are not identical, they are not patentably distinct from each other because each application recites overlapping methods of reducing body weight in humans through administration of AX-15.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (703) 305-3132. The examiner can normally be reached on Monday through Thursday, and alternate Fridays, from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert, C. Hayes, Ph.D.

September 24, 2003

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